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10/706,792	11/12/2003	Todd E. Leonard	4774-111 US	7187

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EXAMINER

VERBITSKY, GAIL KAPLAN

ART UNIT	PAPER NUMBER
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2859

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/29/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/706,792

Applicant(s)

LEONARD ET AL.

Examiner

Gail Verbitsky

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-30 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 02/12/04, 05/10/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Claim objections

1. Claims 13 and 26 are objected to because of the following informalities:

Claim 13: "electron" in line 3 should be replaced with –electronic–,

Claim 26: "deice" in line 4 should be replaced with –device--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. Claims 18 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In this case:

The term "reduced portion" in claim 18 is a relative term, which renders the claim indefinite. The term "reduced portion" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The term "hard plastic material" in claim 22 is a relative term, which renders the claim indefinite. The term "hard plastic material" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 12, 24-26, 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Beret et al. (U.S. 6195581) [hereinafter Beret].

Beret discloses a thermometer/ medical device in combination with a probe cover (intelligent medical device barrier) adapted to be received by a probe of the thermometer, a sensor indicating that the probe cover is "installed" or "not installed", a temperature measuring sensor that is activated when the probe cover is installed. The device is also provided with a warning signal that is issues to inform the user that the probe cover is about to be used twice enabling the user to take appropriate steps to avoid it. This would imply, that the user would replace the probe cover and the measurements would be taken only after the clean probe cover is on. There is a second (temperature) sensor in the probe.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-3, 5-8, 11-15, 17, 19, 24-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Ota (U.S. 6584426).

Ota discloses in Fig. 9 a device/ thermometer/ medical device in combination with a probe cover (intelligent medical device barrier) comprising a temperature sensor (second sensor means) and a probe cover as claimed by applicant. Ota teaches a probe cover detector 9 for detecting presence or absence of the probe cover 2 on a

probe. The probe cover has a flange (collar/ retaining means) 2b with openings/ holes (ID codes, in a broad sense, barcodes) 2a for contacting/ retaining the buttons/ switches 1a on the probe (col. 4, lines 50-65). This would imply that the holes 2a on the probe cover also serve as retaining means providing retaining of buttons 1a of the probe by insert (or detent or protrusion for contacting the buttons/ enable switch). There, inherently, are an electronic unit and an electrical connection between the probe cover ID and the electronic unit. There, inherently, is some device (calibration device), which would recognize the probe cover by a proper code.

The method steps will be met during the normal operation of the device stated above.

6. Claims 1, 3, 12, 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Makita et al. (U.S. 5487607) [hereinafter Makita].

Makita discloses a device/ thermometer/ medical device in combination with a probe cover (intelligent medical device barrier) comprising a temperature sensor (second sensor), the device comprising a probe cover device that is operatively connected to a start switch 30 only when the probe cover C is mounted on probe 2 in an indentation 2a. This would suggest a retaining means on the cover mating with the indentation 2a. Makita teaches a probe cover C detection switch (col. 2, line 38) 40 on the probe. There is a second (temperature) sensor in the probe.

7. Claims 1, 12, 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Kraus et al. (U.S. 6789936) [hereinafter Kraus].

Kraus discloses a device in the field of applicant's endeavor comprising a sensor 4 for determining if a cover is on or off a probe 2. As shown in Fig. 1, upon attachment,

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the probe cover is secured to a portion of the probe containing the switch 4, and the switch 4 is activated when the probe cover is secured on the probe and contacts the switch 4. This would imply that the portion of the probe containing the switch 4 is a retaining means for the probe cover. There is a second (temperature) sensor in the probe.

8. Claims 1, 3, 12, 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Tabata et al. (U.S. 6513970) [hereinafter Tabata].

Tabata discloses a device in the field of applicant's endeavor. Tabata teaches in Fig. 1 that if a probe cover 47 is placed onto a probe 40, a protruding end (protrusion) 61A is pushed by a detent (surface) on the cover against a spring 62 by a ring 48, as the result, contacts 63 turning off a probe cover switch, thereby sensing the presence of the probe cover (col. 8, lines 20-29). This would imply that there is retaining means secured to a thermometer/ medical device that is activated and activates the probe cover switch when the cover is on. There is a second (temperature) sensor in the probe.

9. Claims 1-5, 12-14, 19, 22-27, 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by DeFrank et al. (U.S. 5066142) [hereinafter DeFrank].

DeFrank discloses a device in the field of applicant's endeavor comprising a cover 34 at least partially made of plastic (polyethylene) and having flanges contacting a sensor means/ switch 44 to provide an electrical signal that the probe cover is on by means of pressing onto sensors/ enable switches 32 which are used to disable the thermometer until the used probe cover has been replaced with the other (col. 5). Therefore, DeFrank teaches that the thermometer can be activated only if the probe

cover is in place and not until the used probe cover has been removed and replaced with another (col. 5, lines 50-55). The probe cover has a (hard) plastic collar (frame) 36 contacting the enable switches 32. The device comprises an electronic unit (electrical connection), which, inherently, activates the device upon receiving a signal that a new probe cover is on. The probe cover is retained by annular ribs (retaining means) 30 or friction interference fit to the probe and thus, to the sensors/ enable switches 32 on the probe. There is a second (temperature) sensor in the probe.

The method steps will be met during the normal operation of the device stated above.

10. Claims 1-6, 8, 12-14, 18-27, 29-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Nadeau, Jr. et al. (U.S. 6549794) [hereinafter Nadeau].

Nadeau discloses in Figs. 1-13 a device/ combination of a medical probe and a probe cover (cap) 130/ intelligent medical device barrier comprising all the subject matter disclosed by applicant including a tab 412 which, when removed will break an arm 410. Accordingly a plastic cap/ cover 130 cannot be used more than once. This would imply that, in a broad sense, the fact that the tab is broken serves as an identification/ indication that the cover has been.

The probe cover/ barrier/ cap 130 having a non-reusability unit (identification if the probe has/ has not been previously used). Nadeau teaches (Fig. 12 and col. 10, lines 25-67) a switch that is triggered by movement of a ring 1204 on the probe 120 to indicate to an electronic unit (by electrical connection) 110 that a new probe cover is present. The probe cover/ cap 130 has a retaining means: a collar (guard ring) 1202, a catch/ protrusion means (col. 10, line 35) 1220 that protrudes from the collar/ cap 130,

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catches/ secures the cap 130 on the probe 120 and makes contact with the switch (col. 10, line 61) to start the operation. The probe 120 also comprising a second temperature) sensor.

In another embodiment (Figs. 11), Nadeau teaches to provide the cap 130 with (insertable) fingers (protrusions or detail) 1120 (in the inner surface of the collar, as shown in Figs. 11) which are in a latching/ snap catching position/ displaced to engage with the probe 120 when the cap 130 is mounted onto the probe, and remains in the position preventing the cap 130 to be mounted onto the probe once the cap 130 is removed from the probe 120. Therefore, the cap 130 cannot be reused (col. 10, lines 19-24). It is inherent, that there is some surface/ ledge to engage with the fingers. The method steps will be met during the normal operation of the device stated above.

11. Claims 1, 12, 19, 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Beerwerth et al. (U.S. 6149297) [hereinafter Beerwerth].

Beerwerth discloses in Fig. 1 a device in the field of applicant's endeavor comprising a probe cover having an annular collar 16 which comes in contact with a switch 15 on a medical probe, the switch indicating that the probe cover is on.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 3-4, 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tabata in view of O'Hara et al. (U.S. 4662360) [hereinafter O'Hara].

Tabata discloses the device as stated above.

Tabata does not explicitly teach the limitations of claims 3-4, 6-8.

O'Hara discloses a device in the field of applicant's endeavor (plastic probe cover), the device is comprising retaining means (ring/ collar) having ears (protrusions) 18 for insertion (mating) with a corresponding detent (surface) on a medical device (thermometer) (col. 5, lines 15-18). The retaining means, inherently, provides coupling of the probe cover to the probe, and the switch to the cover.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device, disclosed by Tabata, so as to provide the device with retaining means having hooks and ears, as taught by O'Hara, in order to ensure strong attachment of the cover to the probe during the measurements, as very well known in the art, in order to ensure that the probe is covered and thus, preventing contamination from one patient to another.

14. Claims 9, 15-16, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeFrank in view of Henwood (U.S. 6132086).

DeFrank discloses the device as stated above.

DeFrank does not explicitly teach the limitations of claims 9, 15-16, 28.

Henwood discloses a device in the field of applicant's endeavor wherein Henwood teaches that a probe cover could contain thermosensitive dye/ ink that

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changes its color after being used, and thus, it could be identified by color whether the probe cover has or has not been used.

Therefore, it would have been obvious to one of ordinary skill in the art to modify the probe cover, so as to make it of thermosensitive ink/ dye/ color, as taught by Henwood, in order to provide the user with an instant visual indication that the cover was previously used, so as to prevent contamination from one patient to another. The method steps will be met during the normal operation of the device stated above.

15. Claims 2, 9, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeFrank in view of Kerr (U.S. 6945936).

DeFrank discloses the device as stated above.

DeFrank does not explicitly teach the limitations of claims 2, 9, 18.

Kerr discloses a barrier device (probe cover) for a medical probe having a protruding pull tab 6 which can be used as means of levering the barrier from the probe once used (col. 4, lines 50-53). The device is provided with a color indicator that can be used to indicate that the cover/ barrier is not sterile. This would imply that the color indicator provides the indication that the barrier was used.

Therefore, it would have been obvious to one of ordinary skill in the art to modify the probe cover, so as to make it of thermosensitive ink/ dye/ color, as taught by Kerr, in order to provide the user with a visual indication that the cover was previously used, so as to prevent contamination from one patient to another.

Therefore, it would have been obvious to one of ordinary skill in the art to modify the probe cover, so as to add a pull tab to the probe cover in the device, disclosed by

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DeFrank, in order to make it easier for the user to remove the cover without having expensive ejecting mechanisms and without touching a potentially infectious tip of the probe cover, as suggested by Kerr.

Allowable Subject Matter

16. Claim 10 is objected but would be allowable

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The prior art cited in the PTO-892 and not mentioned above disclose related devices and methods.

Esseff et al. (U.S. 5411032) [hereinafter Esseff] discloses in Figs. 1, 5-6 a probe cover comprising an annular collar (horizontal portion) and legs (detail) 44 for insertion in a corresponding recess (ledge) 48 in a probe adjacent to a piercing switch 50 indicating that the probe cover is on/ off and deforming the cover so as it would not be reused. Also, 46 can hook upon a lip 52 of the probe.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gail Verbitsky whose telephone number is 571/ 272-2253. The examiner can normally be reached on 7:30 to 4:00 ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diego Gutierrez can be reached on 571/ 272-2245. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GKV

Gail Verbitsky
Primary Patent Examiner, TC 2800



December 12, 2006